To: Akerman, Gregory[Akerman.Gregory@epa.gov]

From: Shah, Pv

Sent: Mon 4/25/2016 11:45:08 AM

Subject: FW: Glyphosate animal cancer section

Glyphosate cancer for monograph final 416 16 DAE.docx

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From: David A Eastmond [mailto:david.eastmond@ucr.edu]

Sent: Friday, April 22, 2016 11:18 PM **To:** Shah, Pv <Shah.Pv@epa.gov>

Subject: Glyphosate animal cancer section

Hi Pv:

You have done a nice job summarizing the various studies. My review focused primarily on the cancer results and much less on the other aspects of the studies. Attached is a version of the cancer section with my edits and comments shown in tracking mode. As I read the section, a number of key and interrelated questions came to my attention. 1) What p-value(s) are used by JMPR to determine significance in the cancer bioassay? 2) Are 1- or 2-tailed tests recommended for use? 3) Is a correction such as Bonferroni's recommended for use to control for multiple comparisons? Different critical p-values with and without Bonferroni's correction seem to be used in the document. I think the the committee should agree upon an approach and then use a consistent approach in reviewing the studies.

The IARC evaluation concluded that there was sufficient evidence that glyphosate induced tumors in animals. We may not reach a similar conclusion. If so, I think it is important that when we review the same study as IARC, we specifically address the site recognized by IARC. I think you have do so for the kidney adenomas in the mouse study but I am not sure that the reported increases in pancreatic islet cell tumors in the rat have been addressed.

Please let me know if you have any questions.

Dave

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